



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

AUG 22 1997

Our Reference Number: 95-0794

Mr. Reed W. Simmons  
Genetic Systems Corporation  
6565 185th Avenue NE  
Redmond, WA 98052-5039

Dear Mr. Simmons:

The Center for Biologics Evaluation and Research has completed its review of your request to supplement your product license application for Human Immunodeficiency Virus Types 1 and 2 (Synthetic Peptide), to include the manufacture and sale in interstate and foreign commerce the Genetic Systems HIV-1/HIV-2 Peptide EIA. This in vitro qualitative enzyme immunoassay is to be used for the detection of antibodies to Human Immunodeficiency Virus Types 1 and 2 in human serum or plasma.

Based upon the review of information provided in support of your request, the supplement has been found acceptable.

You are requested to submit samples of each future master lot of the product test kit together with protocols consisting of a summary of essential manufacturing data inclusive of all applicable test results. No master lots of the product test kit shall be distributed until notification of release is received from the Director, Center for Biologics Evaluation and Research (CBER).

The expiration dating for the Genetic Systems HIV-1/HIV-2 Peptide EIA is 12 months when stored at 2-8° C. Any request to extend this dating period must be accompanied by the results of ongoing stability studies.

Any lot of Genetic Systems HIV-1/HIV-2 Peptide EIA found to fall outside of the approved specifications, including expiration dating periods; should be withdrawn from the market. In addition, any reports of significant product defects or product complaints concerning the use of the Genetic Systems HIV-1/HIV-2 Peptide EIA should be submitted to the Office of Compliance, CBER, HFM-650.

If you choose to continue to manufacture and sell in interstate and foreign commerce the viral lysate based Genetic Systems HIV-1/ HIV-2 EIA, the intended use statement contained in the labeling for that product must be revised as follows, "For epidemiologic surveillance using serum, plasma, or dried blood spot (DBS). Not to be used for the screening of blood donors, nor


as an aid in the diagnosis of HIV-1 and/or HIV-2 infection." Other information presented in the labeling must also be modified to reflect this modified intended use. You have 180 days to implement this labeling change.

A copy of your labeling submission for the Genetic Systems HIV-1/HIV-2 Peptide EIA is enclosed. Please submit three copies of final printed labeling at the time of use and include part II of the label transmittal form (Form FDA 2567) with completed implementation information.

In addition, please submit three copies of the proposed introductory advertising and promotional labeling. You may wish to submit the proposed materials in draft form with an FDA form 2567 to CBER, Advertising and Promotional Labeling Staff, HFM-202. Promotional claims should be consistent with and not contrary to approved labeling. No comparative claims or claim of superiority over other similar products should be made unless data to support such claims are submitted to and approved by CBER.

This information will be placed on file with your product license application for Human Immunodeficiency Virus Types 1 and 2 (Synthetic Peptide).

Sincerely yours,

  
fw Jay S. Epstein, M.D.  
Director

Office of Blood Research and Review  
Center for Biologics  
Evaluation and Research